

(19)日本国特許庁 (J P)

(12) 公開特許公報 (A)

(11)特許出願公開番号

特開2001-116744

(P2001-116744A)

(43)公開日 平成13年4月27日(2001.4.27)

(51) Int.Cl.⁷

識別記号

FI

テーマコード* (参考)

G O I N 33/15

G O I N 33/15

$$\mathbf{z}$$

G O 6 F 19/00

G O 6 F 15/42

A

審査請求 有 請求項の数 3 OL (全 5 頁)

(21)出願番号 特願平11-295910

(22)出願日 平成11年10月18日(1999. 10. 18)

(71)出題人 399068041

株式会社エイチ・アンド・ティー
大阪府東大阪市森河内西2丁目20-4

(71)出願人 599146886

濱田 孝治
東大阪市森河内西2-20-4

(72)発明者 濱田 孝治

東大阪市森河内西 2-20-4

(74)代理人 100109472

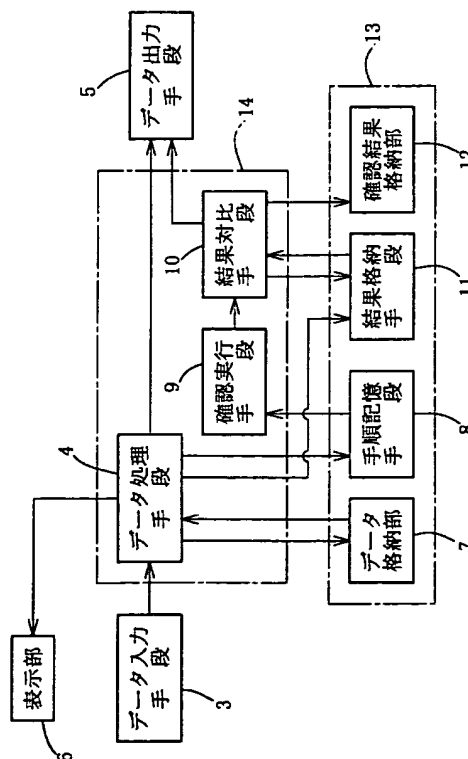
弁理士 森本 直之

(54) 【発明の名称】 薬品試験データ管理システム

(57) 【要約】

【課題】システム運用中の動作確認を自動的に行之、確実に G L P等を保証することのできる薬品試験データ管理システムを提供する。

【解決手段】薬品を生体に投与した際の生体の症状変化等のデータを管理する薬品試験データ管理システムであって、動作確認の手順を記憶する手順記憶手段8と、上記動作確認の結果を格納する結果格納手段11と、上記手順記憶手段8に記憶された動作確認の手順にしたがって自動的に動作確認を実行する確認実行手段9と、上記確認実行手段9による動作確認の結果を、結果格納手段11に格納されている動作確認の結果と対比する結果対比手段10とを備えることにより、2回目の動作確認からは、確認実行手段9で自動的に動作確認を行い、その結果を、結果格納手段11に格納されている受入検査時の動作確認の結果と対比して検査結果の判定を行うことができるようになった。



【特許請求の範囲】

【請求項1】 薬品を生体に投与した際の生体の症状変化等のデータを管理する薬品試験データ管理システムであって、動作確認の手順を記憶する手順記憶手段と、上記動作確認の結果を格納する結果格納手段と、上記手順記憶手段に記憶された動作確認の手順にしたがって自動的に動作確認を実行する確認実行手段と、上記確認実行手段による動作確認の結果を、結果格納手段に格納されている動作確認の結果と対比する結果対比手段とを備えていることを特徴とする薬品試験データ管理システム。

【請求項2】 手順記憶手段がシステム導入時に行われる動作確認の手順を記憶するとともに、結果格納手段が上記システム導入時の動作確認の結果を格納するようになっている請求項1記載の薬品試験データ管理システム。

【請求項3】 生体として動物を用いた薬品の毒性試験に用いられるものである請求項1または2記載の薬品試験データ管理システム。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、薬品を生体に投与した際の生体の症状変化等を記録する薬品試験データ管理システムに関するものである。

【0002】

【従来の技術】医薬品・農薬・食品添加物・その他化学物質の発癌性や毒性等、人体に対する安全性は、市販に先だって臨床試験が行われるが、臨床試験に入る前に、ラットやマウス等の動物を使用する非臨床試験で確認することが行われている。

【0003】このような動物を使用した薬品等の安全性試験は、1回あたりどの程度投与すれば毒性が発生し、その毒性の特徴が何かを明かにする単回投与毒性試験、反復投与時に毒性が見とめられる用量と毒性変化が見とめられない用量および毒性の特徴を明らかにする反復投与毒性試験、親動物の生殖に及ぼす影響や次世代の発生に関する影響等を明らかにする生殖・発生毒性試験、DNAに傷害性を示す物質や突然変異を誘発する性質の有無を明らかにする変異原性試験をはじめ、がん原性試験、皮膚感作性試験、皮膚光感作性試験、依存性試験等の各種の試験が行われる。

【0004】上記各試験は、薬品を実際に動物に投与し、体重、餌、水、尿等の量の測定や生化学検査、血液学的検査、臨床症状の観察、各種の病理所見等を行い、採取したデータを分析することによって行われる。

【0005】このような安全性試験は、その薬品を実際に人体に投与して行う臨床試験に先立って行われ、最終的には人体に影響を及ぼすものであることから、薬品が生体に及ぼす影響を正確に理解し、分析することが必要になる。このため、データの記録や管理・分析には、従来からコンピュータシステムが用いられてきた。

【0006】上述したように、医薬品をはじめとする薬品は、人体に影響を与えるものであるため、上記のような安全性試験のデータ管理には、データに改ざんが加えられることのないよう、厚生省をはじめとする各官庁で厳しい基準が設けられている。このような規準は、総称して「GLP (Good Laboratory Practice)」と呼ばれ、当然のことながら、データを管理するコンピュータシステムもGLPの規準を満たしている必要がある。

【0007】そして、上記システムは、システムの設計自体がGLPに適合している必要があるのは言うまでもないが、システムを導入した際に、GLPに適合して確実に動作するか否かを確認する導入時の動作確認（受入検査）が必要である。GLPでは、システムの不備はシステムの受け入れ側にあるということになっており、受入検査が極めて重要視されている。一方、上記のような動作確認は、導入時だけでなく、システム運用中にも、一定期間ごとやあるいはシステムの一部にバージョンアップがあったような場合には、GLPに適合して確実に動作することを再度確認して文書として残し、データの改ざんだけでなく、システム自体にも改ざんがないことを保証しなければならない。

【0008】

【発明が解決しようとする課題】

【0009】しかしながら、従来のシステムでは、動作確認にかなりの時間と手間を要し、通常のシステムでは2～3名の人員で3ヶ月以上の時間をかけて行わなければならない。このため、システム導入時の受入検査は行われるものの、一旦システムが稼動をはじめると、定期的な動作確認等は全く行われていなかったのが実情である。このような事情から、ソフトウェア自体は汎用のハードウェアで利用できるものの、汎用機を用いると、オペレーションシステムや連携していない他のソフトウェアのアップデートだけでも動作確認が必要になってしまうため、実質的には専用機を準備しなければならない、このため、システムの導入コストも非常に高いものとなっていた。

【0010】本発明は、このような事情に鑑みなされたもので、システム運用中の動作確認を自動的に行い、確実にGLP等を保証することのできる薬品試験データ管理システムの提供を目的とする。

【0011】

【課題を解決するための手段】上記の目的を達成するため、本発明の薬品試験データ管理システムは、薬品を生体に投与した際の生体の症状変化等のデータを管理する薬品試験データ管理システムであって、動作確認の手順を記憶する手順記憶手段と、上記動作確認の結果を格納する結果格納手段と、上記手順記憶手段に記憶された動作確認の手順にしたがって自動的に動作確認を実行する確認実行手段と、上記確認実行手段による動作確認の結

果を、結果格納手段に格納されている動作確認の結果と対比する結果対比手段とを備えていることを要旨とする。

【0012】すなわち、本発明の薬品試験データ管理システムは、動作確認の手順を記憶する手順記憶手段と、上記動作確認の結果を格納する結果格納手段と、上記手順記憶手段に記憶された動作確認の手順にしたがって自動的に動作確認を実行する確認実行手段と、上記確認実行手段による動作確認の結果を、結果格納手段に格納されている動作確認の結果と対比する結果対比手段とを備えている。このため、例えば、システム導入時の受入検査の際に行った動作確認の手順を記憶するとともに、その検査結果を格納する。そして、2回目の動作確認からは、確認実行手段で自動的に動作確認を行い、その結果を、結果格納手段に格納されているシステム導入時の動作確認の結果と対比して検査結果の判定を行うことができる。

【0013】このように、2回目以降の動作確認を自動的に行うことにより、従来2～3名の人員で3ヶ月以上の時間を要していたものが、1晩足らずで終了するようになる。したがって、システム運用中の定期的な動作確認だけでなく、オペレーションシステムや連携していない他のソフトウェアをアップデートした際にも、頻繁に動作確認を行い、確実にG L P等を保証することができるようになる。また、こまめに動作確認できるため、汎用機を使用できるようになり、システムの導入コストを大幅に引き下げることができる。

【0014】本発明の薬品試験データ管理システムにおいて、手順記憶手段がシステム導入時に行われる動作確認の手順を記憶するとともに、結果格納手段が上記システム導入時の動作確認の結果を格納するようになっている場合には、受け入れ検査時に必然的に行われる動作確認の手順を記憶して2回目以降の動作確認を行うため、画一的なパッケージシステムではなく、システム受け入れ先ごとにカスタマイズされたシステムであっても、2回目以降、各受け入れ先ごとに必要な動作確認を自動的に行うことができるようになる。

【0015】本発明の薬品試験データ管理システムにおいて、生体として動物を用いた薬品の毒性試験に用いられるものである場合には、生体として動物を用いた薬品の毒性試験が、膨大で多種多様なデータ処理が必要であることから、システムの導入コストが低いことが求められ、汎用機を使用できる効果が顕著で効果的である。

【0016】

【発明の実施の形態】つぎに、本発明の実施の形態を詳しく説明する。

【0017】図1は、本発明の薬品試験データ管理システムの一実施の形態を示すシステム構成図である。このシステムは、薬品を実際に動物に投与したときの体重、餌、水、尿等の量や臨床所見等各種のデータを入力する

データ入力手段3と、このデータ入力手段3に入力されたデータを受信して、集計等の処理を行うデータ処理手段4と、上記データ処理手段4を経由して、入力されたデータや集計結果等を格納するデータ格納部7とを備えている。図において、13はハードディスク等の記憶装置であり、14は中央演算装置およびメモリ等を備えたコンピュータ装置である。

【0018】また、上記データ処理手段4で集計等されたデータを帳票等に出力するデータ出力手段5と、データ入力時やデータ出力時に各種の情報を表示する表示部6が設けられている。

【0019】ここで、上記システムは、上述した各手段により、通常の運用が行われるようになっている。また、システムの運用に入る前のシステム導入時に行われる受入検査は、各種のデータをデータ入力手段3に実際に入力し、データ処理手段4に集計等を行わせ、正確な集計結果が得られることを確認するとともに、得られた正確な集計結果を記録として残すことにより行われる。

【0020】受入検査の結果は、結果格納手段11に格納されて保管されるとともに、データ出力手段から出力された帳票類としても保存される。

【0021】そして、上記システムには、上述した受入検査時の動作確認の手順を記憶する手順記憶手段8と、この手順記憶手段8に記憶された動作確認手順を読み出して自動的に実行する確認実行手段9が設けられている。この確認実行手段9では、受入検査終了後、任意の時に、上記受入検査と同じ手順で2回目以降の動作確認が行われる。

【0022】また、上記システムには、上記確認実行手段9で実行された動作確認結果を受信して、結果格納手段11に格納されている受入検査時の動作確認結果と対比する結果対比手段10が設けられている。さらに、上記システムには、結果対比手段10で対比された対比結果を動作確認結果とともに格納する確認結果格納部12が設けられている。また、上記対比結果ならびに動作確認結果は、データ出力手段5から出力されるようになっている。

【0023】つぎに、上記薬品試験データ管理システムの動作について、図2に示すフローチャートをもとに説明する。なお、図において「S」は、ステップを意味する。

【0024】まず、システムの導入時に、受入検査が開始される(S1)。この受入検査では、体重、餌、水、尿等の量や病理所見等のデータがデータ入力手段3に入力され、データ処理手段4に集計等を行わせて正確な集計結果が得られることを確認する。

【0025】このとき、手順記憶手段8では、上記受入検査の動作手順の記憶が行われる(S2)。具体的には、体重、餌、水等のデータ入力と、入力されたデータの集計等の処理の手順が記憶される。そして、入力され

たデータの正確な集計結果が確認され、受入検査が終了すると、受入検査での動作確認結果が結果格納手段11に格納される(S3)。

【0026】受入検査が終了すると、システムの実際の運用が開始される(S4)。そして、通常の業務内では、2回目以降の動作確認を実行せずにシステムの運用が続けられる。

【0027】2回目以降の動作確認を実行する場合は、手順記憶手段に記憶されている受入検査時の動作確認手順を読み出し(S5～S6)、確認実行手段9により、受入検査で行ったのとまったく同じ手順で、体重、餌、水等のデータ入力と、入力されたデータの集計等の処理等が実行される(S7)。

【0028】そして、動作確認の実行後、結果対比手段10により、今回の動作確認結果を結果格納手段11に格納されている受入検査の動作確認結果と対比することが行われる(S8)。ここで、今回の動作確認において、受入検査時の動作確認結果と同じ結果が得られたか否かの判定が自動的に行われる。

【0029】ついで、今回の動作確認結果および対比結果を、データ出力手段5で出力するとともに(S9)、確認結果格納部12に格納し保存することが行われる(S10)。そして、ステップ4に戻り、再び通常のシステム運用が開始される。

【0030】このように、上記薬品試験データ管理システムによれば、2回目以降の動作確認を自動的に行うことにより、従来2～3名の人員で3ヶ月以上の時間を要していたものが、1晩足らずで終了するようになる。したがって、システム運用中の定期的な動作確認だけでなく、オペレーションシステムや連携していない他のソフトウェアをアップデートした際にも、頻繁に動作確認を行い、確実にGLP等を保証することができるようになる。また、こまめに動作確認できるため、汎用機を使用できるようになり、システムの導入コストを大幅に引き下げることができる。

【0031】また、受け入れ検査時に必然的に行われる動作確認の手順を記憶して2回目以降の動作確認を行うため、画一的なパッケージシステムではなく、システム受け入れ先ごとにカスタマイズされたシステムであっても、各受け入れ先ごとに必要な動作確認を2回目以降自動的に行うことができる。

【0032】このような薬品試験データ管理システムは、生体として動物を用いた薬品の毒性試験に好適に用いられる。生体として動物を用いた薬品の毒性試験が、膨大で多種多様なデータ処理が必要であることから、システムの導入コストが低いことが求められ、汎用機を使用できる効果が顕著で効果的だからである。

【0033】なお、上記実施の形態では、結果格納手段

11に、システム導入時の受入検査の動作確認結果を格納し、2回目以降の動作確認において、動作確認結果を上記受入検査時の動作確認結果と対比するようにしたが、これに限定するものではなく、結果格納手段11に、2回目以降の動作確認結果をそのつど格納し、次の動作確認において、動作確認結果を前回の動作確認結果と対比するようにしてもよい。

【0034】また、上記実施の形態では、手順記憶手段8に、システム導入時の受入検査の動作確認手順を記憶し、2回目以降の動作確認において、上記受入検査時の動作手順で動作確認を行うようにしたが、これに限定するものではなく、手順記憶手段8に、2回目以降の動作確認手順をそのつど記憶し、次の動作確認において、前回の動作確認手順で動作確認を行うようにしてもよい。

【0035】また、本発明のシステムは、生体として動物を用いた薬品の毒性試験だけに限らず、動物による安全性試験に入る前の薬効薬理試験や一般薬理試験、薬物動体試験、あるいは、GCP(医薬品の臨床試験の実施に関する基準)が適用される臨床試験等にも応用することができる。また、非GLPの試験に応用することも可能である。これらの場合でも、同様の作用効果を奏する。

【0036】なお、本発明において、薬品とは、医薬品に限定されるものではなく、農薬、食品添加物、皮膚外用剤をはじめ、各種の化学物質を含む趣旨である。

【0037】

【発明の効果】以上のように、本発明の薬品試験データ管理システムによれば、2回目以降の動作確認を自動的に行うことにより、従来2～3名の人員で3ヶ月以上の時間を要していたものが、1晩足らずで終了するようになる。したがって、システム運用中の定期的な動作確認だけでなく、オペレーションシステムや連携していない他のソフトウェアをアップデートした際にも、頻繁に動作確認を行い、確実にGLP等を保証することができるようになる。また、こまめに動作確認できるため、汎用機を使用できるようになり、システムの導入コストを大幅に引き下げることができる。

【図面の簡単な説明】

【図1】本発明の薬品試験データ管理システムの一実施の形態を示すシステム構成図である。

【図2】上記薬品試験データ管理システムの動作を説明するフローチャート図である。

【符号の説明】

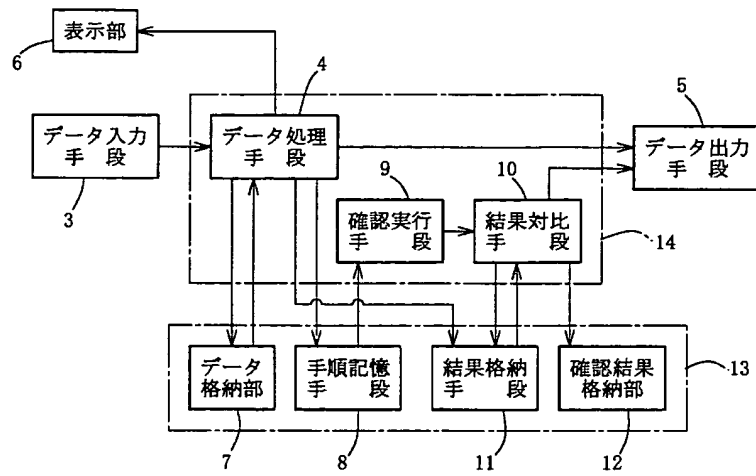
8 手順記憶手段

9 確認実行手段

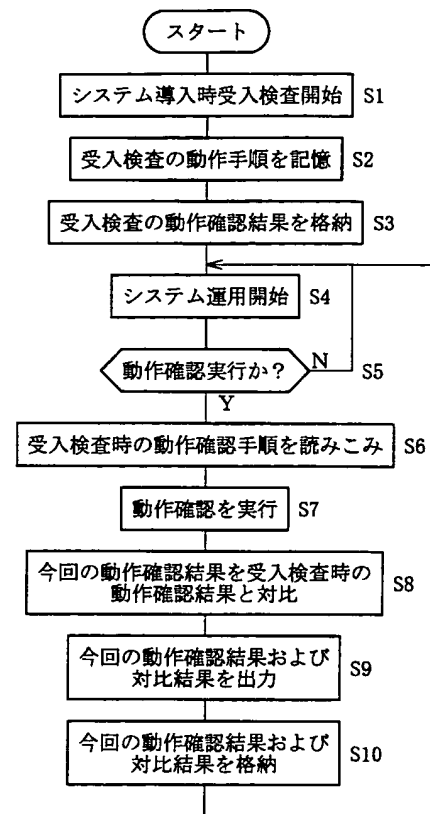
10 結果対比手段

11 結果格納手段

【図1】



【図2】



PATENT ABSTRACTS OF JAPAN

(11)Publication number : 2001-116744

(43)Date of publication of application : 27.04.2001

(51)Int.Cl.

G01N 33/15

G06F 19/00

(21)Application number : 11-295910

(71)Applicant : H & T:KK
HAMADA KOJI

(22)Date of filing : 18.10.1999

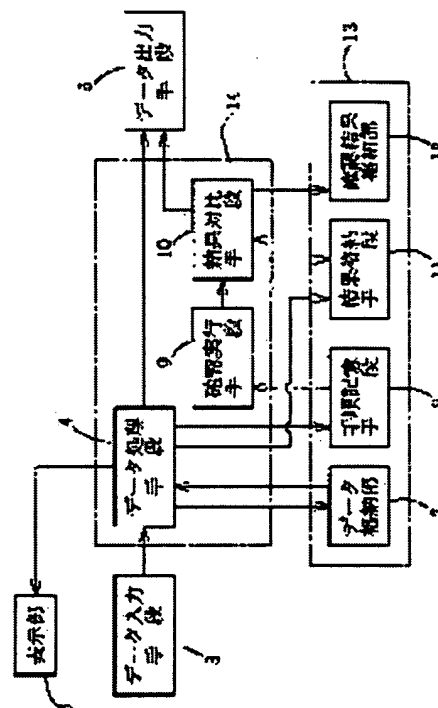
(72)Inventor : HAMADA KOJI

(54) CONTROL SYSTEM FOR DATA ON DRUG TEST

(57)Abstract:

PROBLEM TO BE SOLVED: To provide a control system, for data on a drug test, in which an operation confirmation during a system operation is performed automatically and by which a GPL or the like can be guaranteed surely.

SOLUTION: In this control system for data on a drug test, data on a change or the like in the symptom of a living body at a time when the living body is dosed with a drug is controlled. A procedure storage means 8 which stores the procedure of an operation confirmation is provided. A result storage means 11 which stores the result of the operation confirmation is provided. A confirmation execution means 9 which automatically executes the operation confirmation according to the procedure of the operation confirmation stored in the procedure storage means 8 is provided. A result comparison means 10 by which the result of the operation confirmation by the confirmation execution means 9 is compared with the result of the operation confirmation stored in the result storage means 11 is provided. Thereby, from a second operation confirmation onward, the operation confirmation is performed automatically by the confirmation execution means 9, its result is compared with the result of an operation confirmation in an acceptance inspection stored in the result storage means 11, and an inspection result can be judged.



LEGAL STATUS

[Date of request for examination] 18.10.1999

[Date of sending the examiner's decision of rejection]

[Kind of final disposal of application other than the examiner's decision of rejection or application converted registration]

[Date of final disposal for application]

[Patent number] 3291717

[Date of registration] 29.03.2002

[Number of appeal against examiner's decision of rejection]

[Date of requesting appeal against examiner's decision]

of rejection]

[Date of extinction of right]

16.10.2003

THIS PAGE BLANK (USPTO)

*** NOTICES ***

JPO and NCIPi are not responsible for any damages caused by the use of this translation.

- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.**** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

CLAIMS

[Claim(s)]

[Claim 1] A procedure storage means to manage data, such as symptom change of the living body at the time of medicating a living body with a chemical, and to be a chemical trial data management system and to memorize the procedure of a check of operation, A check activation means to perform a check of operation automatically according to the procedure of the check of operation memorized by the storing means and the above-mentioned procedure storage means as a result of storing the result of the above-mentioned check of operation, The chemical trial data management system characterized by having the contrast means as a result of contrasting the result of the check of operation by the above-mentioned check activation means with the result of the check of operation in which it is stored by the result storing means.

[Claim 2] The chemical trial data management system according to claim 1 which stores the result of the check of a result storing means of operation at the time of the above-mentioned system installation while memorizing the procedure of a check of operation in which a procedure storage means is performed at the time of system installation.

[Claim 3] The chemical trial data management system according to claim 1 or 2 which is what is used for the toxicity test of the chemical using the animal as a living body.

[Translation done.]

*** NOTICES ***

JPO and NCIP are not responsible for any damages caused by the use of this translation.

- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.**** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Field of the Invention] This invention relates to the chemical trial data management system which records symptom change of the living body at the time of medicating a living body with a chemical etc.

[0002]

[Description of the Prior Art] In addition to this, checking them by the nonclinical test which uses animals, such as a rat and a mouse, before drugs, agricultural chemicals and a food additive, and safeties to the body, such as carcinogenic, toxicity, etc. of a chemical, go into a clinical trial although a clinical trial is performed in advance of marketing is performed.

[0003] Safety tests, such as a chemical which used such an animal The single-dose toxicity study to which toxicity will occur if a medicine is prescribed for the patient how much per time, and the toxic description carries out something for whether being **, The repeated-dose toxicity study which clarifies the dosage and the toxic description that the dosage and a toxic change to which toxicity sees and is stopped at the time of repeated-dose administration see, and are not stopped, The reproduction test which clarifies effect affect reproduction of a parent animal, effect about next-generation generating, etc., The mutagenicity test which clarifies existence of the property which induces the matter which shows trauma nature to DNA, and mutation is begun, and various kinds of trials, such as a carcinogenicity trial, a skin sensitization test, skin photosensitization study, and dependence study, are performed.

[0004] Each above-mentioned trial actually medicates an animal with a chemical, and is performed by analyzing the data which extracted by performing measurement of the amount of weight, food, water, urine, etc., biochemical inspection and hemology-inspection, observation of a clinical manifestation, various kinds of pathological findings, etc.

[0005] Since such a safety test is performed in advance of the clinical trial which actually medicates the body with the chemical and performs it and the body is finally affected, it is necessary to understand correctly the effect a chemical affects a living body, and to analyze it. For this reason, the computer system has been used for record, and management and analysis of data from the former.

[0006] As mentioned above, since chemicals including drugs are what affects the body, severe criteria are prepared in the data control of the above safety tests in each government office including the Ministry of Health and Welfare so that an alteration may not be added to data. Such a standard is named generically, and is called "GLP (Good Laboratory Practice)", and the computer system which manages data with a natural thing also needs to fulfill the standard of GLP.

[0007] And although it cannot be overemphasized that the design of a system itself needs to conform to GLP, when the above-mentioned system introduces a system, it needs the check of operation at the time of the installation which checks whether GLP is suited and it operates certainly (acceptance inspection). In GLP, it is to be said that the defect of a system is in the acceptance side of a system, and importance is extremely attached to the acceptance inspection. the checks [above on the other hand] of operation -- not only the time of installation but the inside of systems operation -- every fixed period -- or when some systems have version up, it must check suiting GLP and operating certainly again, must leave as a document, and must guarantee that there is no alteration not only in the alteration of data but in the system itself.

[0008]

[Problem(s) to be Solved by the Invention]

[0009] However, by the conventional system, the check of operation had to take remarkable time amount and

time and effort, and it had to carry out over the time amount for three months or more at the staff of 2 – trinominal in the usual system. For this reason, although the acceptance inspection at the time of system installation is conducted, once a system begins operation, the actual condition is that the periodical check of operation etc. was not performed at all. The software itself had become what also has the introductory, very high cost of a system from such a situation, in order that [this] at least update of operation system or other software which is not in cooperation might prepare a special-purpose machine substantially since a check of operation is needed if a general aviation is used although it can be used by general-purpose hardware.

[0010] This invention was made in view of such a situation, performs the check of operation in systems operation automatically, and aims at offer of the chemical trial data management system which can guarantee GLP etc. certainly.

[0011]

[Means for Solving the Problem] In order to attain the above-mentioned purpose, the chemical trial data management system of this invention A procedure storage means to manage data, such as symptom change of the living body at the time of medicating a living body with a chemical, and to be a chemical trial data management system and to memorize the procedure of a check of operation, A check activation means to perform a check of operation automatically according to the procedure of the check of operation memorized by the storing means and the above-mentioned procedure storage means as a result of storing the result of the above-mentioned check of operation, Let it be a summary to have the contrast means, as a result of contrasting the result of the check of operation by the above-mentioned check activation means with the result of the check of operation in which it is stored by the result storing means.

[0012] Namely, the chemical trial data management system of this invention As a result of storing a procedure storage means to memorize the procedure of a check of operation, and the result of the above-mentioned check of operation, a storing means, It has the contrast means, as a result of contrasting with the result of the check of operation in which the result of the check of operation by check activation means to perform a check of operation automatically according to the procedure of the check of operation memorized by the above-mentioned procedure storage means, and the above-mentioned check activation means is stored by the result storing means. For this reason, that inspection result is both stored as if the procedure of the check of operation on the occasion of the acceptance inspection at the time of system installation is memorized for example. And from the 2nd check of operation, a check activation means can perform a check of operation automatically, and an inspection result can be judged as contrasted with the result of the check of operation at the time of the system installation in which the result is stored by the result storing means.

[0013] Thus, what the staff of 2 – trinominal had taken the time amount for three months or more conventionally comes to be completed by 1 ***** by performing the check of the 2nd henceforth of operation automatically. Therefore, not only the periodical check of operation in systems operation but when it updates operation system and other software which is not in cooperation, a check of operation can be performed frequently and GLP etc. can be guaranteed certainly. Moreover, since a check of operation can be carried out at eye the top, a general aviation can be used now and the introductory cost of a system can be reduced sharply.

[0014] While memorizing the procedure of a check of operation in which a procedure storage means is performed at the time of system installation, in the chemical trial data management system of this invention In storing the result of the check of a result storing means of operation at the time of the above-mentioned system installation In order to memorize the procedure of the check of operation inevitably performed at the time of a receiving inspection and to perform the check of the 2nd henceforth of operation, Even if it is not a uniform package system but the system customized for every system acceptance place, a required check of operation can be automatically performed for every acceptance place 2nd henceforth.

[0015] In the chemical trial data management system of this invention, since data processing with the huge and various toxicity test of the chemical which used the animal as a living body is required to be what is used for the toxicity test of the chemical using the animal as a living body, the effectiveness that it is called for that the introductory cost of a system is low and it can use a general aviation is remarkable, and effective.

[0016]

[Embodiment of the Invention] Below, the gestalt of operation of this invention is explained in detail.

[0017] Drawing 1 is the system configuration Fig. showing the gestalt of 1 operation of the chemical trial data management system of this invention. This system is equipped with the data storage section 7 which stores

the inputted data, a total result, etc. via a data input means 3 to input various kinds of data, such as an amount, clinical findings, etc. of the weight when actually medicating an animal with a chemical, food, water, urine, etc., a data-processing means 4 to receive the data inputted into this data input means 3, and to process a total etc., and the above-mentioned data-processing means 4. In drawing, 13 is storage, such as a hard disk, and 14 is the computer apparatus equipped with a central processing unit, memory, etc.

[0018] Moreover, the display 6 which displays various kinds of information as a data output means 5 to output to a document etc. the data to which the total etc. was carried out with the above-mentioned data-processing means 4, at the time of a data input and data output is formed.

[0019] Here, the usual employment is performed by each means which mentioned the above-mentioned system above. Moreover, the acceptance inspection conducted at the time of the system installation before going into employment of a system actually inputs various kinds of data into the data input means 3, makes a total etc. carry out to the data-processing means 4, and it is conducted by leaving the obtained exact total result as record while checking that an exact total result is obtained.

[0020] The result of an acceptance inspection is saved also as electronic forms outputted from the data output means while being stored in the result storing means 11 and kept.

[0021] And a procedure storage means 8 to memorize the procedure of the check of operation at the time of the acceptance inspection mentioned above, and a check activation means 9 to read the verification procedure of operation memorized by this procedure storage means 8, and to perform automatically are formed in the above-mentioned system. With this check activation means 9, the check of the 2nd henceforth of operation is performed after acceptance-inspection termination by the same procedure as the above-mentioned acceptance inspection at the time of arbitration.

[0022] Moreover, the check result of operation performed with the above-mentioned check activation means 9 is received, and as a result of contrasting with the check result of operation at the time of the acceptance inspection stored in the result storing means 11, the contrast means 10 is formed in the above-mentioned system. Furthermore, the check result storing section 12 which stores in the above-mentioned system the contrast result contrasted with the result contrast means 10 with a check result of operation is formed. Moreover, the above-mentioned contrast result and a check result of operation are outputted from the data output means 5.

[0023] Below, actuation of the above-mentioned chemical trial data management system is explained based on the flow chart shown in drawing 2. In addition, in drawing, "S" means a step.

[0024] First, an acceptance inspection is started at the time of installation of a system (S1). By this acceptance inspection, it checks that data of weight, food, water, urine, etc., such as an amount and pathological findings, are inputted into the data input means 3, make a total etc. carry out to the data-processing means 4, and an exact total result is obtained.

[0025] At this time, storage of the operations sequence of the above-mentioned acceptance inspection is performed with the procedure storage means 8 (S2). Specifically, the procedure of processings, such as a total of the data inputted as data inputs, such as weight, food, and water, is memorized. And after the exact total result of the inputted data is checked and an acceptance inspection is completed, the check result of operation in an acceptance inspection is stored in the result storing means 11 (S3).

[0026] Termination of an acceptance inspection starts actual operation of a system (S4). And employment of a system is continued within the usual business, without performing the check of the 2nd henceforth of operation.

[0027] When performing the check of the 2nd henceforth of operation, the verification procedure of operation at the time of the acceptance inspection memorized by the procedure storage means is read (S5-S6), and processing of a total of the data which are the completely same procedure as the acceptance inspection performed, and were inputted as data inputs, such as weight, food, and water, by the check activation means 9 etc. is performed (S7).

[0028] And contrasting with the check result of the acceptance inspection in which this check result of operation is stored by the result storing means 11 of operation with the contrast means 10 a result is performed after activation of a check of operation (S8). Here, in this check of operation, the judgment of whether the same result as the check result of operation at the time of an acceptance inspection was obtained is performed automatically.

[0029] Subsequently, storing and saving them in (S9) check result storing section 12, while outputting this

check result of operation and contrast result with the data output means 5 is performed (S10). And return and the usual systems operation are again started by step 4.

[0030] Thus, according to the above-mentioned chemical trial data management system, what the staff of 2 – trinomial had taken the time amount for three months or more conventionally comes to be completed by 1 ***** by performing the check of the 2nd henceforth of operation automatically. Therefore, not only the periodical check of operation in systems operation but when it updates operation system and other software which is not in cooperation, a check of operation can be performed frequently and GLP etc. can be guaranteed certainly. Moreover, since a check of operation can be carried out at eye the top, a general aviation can be used now and the introductory cost of a system can be reduced sharply.

[0031] Moreover, in order to memorize the procedure of the check of operation inevitably performed at the time of a receiving inspection and to perform the check of the 2nd henceforth of operation, even if it is not a uniform package system but the system customized for every system acceptance place, a required check of operation can be automatically performed for every acceptance place 2nd henceforth.

[0032] Such a chemical trial data management system is used suitable for the toxicity test of the chemical which used the animal as a living body. It is because the effectiveness that it is called for that the introductory cost of a system is low and it can use a general aviation since data processing with the huge and various toxicity test of the chemical using the animal as a living body is required is remarkable and effective.

[0033] In addition, although the check result of the acceptance inspection at the time of system installation of operation is stored in the result storing means 11 and the check result of operation was contrasted with the check result of operation at the time of the above-mentioned acceptance inspection in the check of the 2nd henceforth of operation with the gestalt of the above-mentioned implementation The check result of the 2nd henceforth of operation is stored in the storing means 11 each time, and you may make it contrast a check result of operation with the last check result of operation in a next check of operation not the thing to limit to this but a result.

[0034] Moreover, although the verification procedure of the acceptance inspection at the time of system installation of operation is memorized for the procedure storage means 8 and the operations sequence at the time of the above-mentioned acceptance inspection was made to perform a check of operation for it in the check of the 2nd henceforth of operation with the gestalt of the above-mentioned implementation The verification procedure of the 2nd henceforth of operation is memorized for the procedure storage means 8 instead of what is limited to this each time, and it may be made to carry out a check of operation to it by the last verification procedure of operation in a next check of operation.

[0035] Moreover, the system of this invention is applicable to the toxicity test of the chemical which used the animal as a living body, a drug effect pharmacological test and a general pharmacological test before going into the safety test by the animal, a drug dynamic body trial, or the clinical trial to which GCP (Good Clinical Practice of drugs) is applied. Moreover, applying to the trial of non-GLP is also possible. The same operation effectiveness is done so also by these cases.

[0036] In addition, in this invention, a chemical is the meaning which is not limited to drugs and contains various kinds of chemicals including agricultural chemicals, a food additive, and skin external preparations.

[0037] [Effect of the Invention] As mentioned above, according to the chemical trial data management system of this invention, what the staff of 2 – trinomial had taken the time amount for three months or more conventionally comes to be completed by 1 ***** by performing the check of the 2nd henceforth of operation automatically. Therefore, not only the periodical check of operation in systems operation but when it updates operation system and other software which is not in cooperation, a check of operation can be performed frequently and GLP etc. can be guaranteed certainly. Moreover, since a check of operation can be carried out at eye the top, a general aviation can be used now and the introductory cost of a system can be reduced sharply.

[Translation done.]

*** NOTICES ***

JPO and NCIPi are not responsible for any damages caused by the use of this translation.

- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.*** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

TECHNICAL FIELD

[Field of the Invention] This invention relates to the chemical trial data management system which records symptom change of the living body at the time of medicating a living body with a chemical etc.

[Translation done.]

*** NOTICES ***

JPO and NCIP are not responsible for any damages caused by the use of this translation.

- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.**** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

PRIOR ART

[Description of the Prior Art] In addition to this, checking them by the nonclinical test which uses animals, such as a rat and a mouse, before drugs, agricultural chemicals and a food additive, and safeties to the body, such as carcinogenic, toxicity, etc. of a chemical, go into a clinical trial although a clinical trial is performed in advance of marketing is performed.

[0003] Safety tests, such as a chemical which used such an animal The single-dose toxicity study to which toxicity will occur if a medicine is prescribed for the patient how much per time, and the toxic description carries out something for whether being **, The repeated-dose toxicity study which clarifies the dosage and the toxic description that the dosage and a toxic change to which toxicity sees and is stopped at the time of repeated-dose administration see, and are not stopped, The reproduction test which clarifies effect affect reproduction of a parent animal, effect about next-generation generating, etc., The mutagenicity test which clarifies existence of the property which induces the matter which shows trauma nature to DNA, and mutation is begun, and various kinds of trials, such as a carcinogenicity trial, a skin sensitization test, skin photosensitization study, and dependence study, are performed.

[0004] Each above-mentioned trial actually medicates an animal with a chemical, and is performed by analyzing the data which extracted by performing measurement of the amount of weight, food, water, urine, etc., biochemical inspection and hemology-inspection, observation of a clinical manifestation, various kinds of pathological findings, etc.

[0005] Since such a safety test is performed in advance of the clinical trial which actually medicates the body with the chemical and performs it and the body is finally affected, it is necessary to understand correctly the effect a chemical affects a living body, and to analyze it. For this reason, the computer system has been used for record, and management and analysis of data from the former.

[0006] As mentioned above, since chemicals including drugs are what affects the body, severe criteria are prepared in the data control of the above safety tests in each government office including the Ministry of Health and Welfare so that an alteration may not be added to data. Such a standard is named generically, and is called "GLP (Good Laboratory Practice)", and the computer system which manages data with a natural thing also needs to fulfill the standard of GLP.

[0007] And although it cannot be overemphasized that the design of a system itself needs to conform to GLP, when the above-mentioned system introduces a system, it needs the check of operation at the time of the installation which checks whether GLP is suited and it operates certainly (acceptance inspection). In GLP, it is to be said that the defect of a system is in the acceptance side of a system, and importance is extremely attached to the acceptance inspection. the checks [above on the other hand] of operation -- not only the time of installation but the inside of systems operation -- every fixed period -- or when some systems have version up, it must check suiting GLP and operating certainly again, must leave as a document, and must guarantee that there is no alteration not only in the alteration of data but in the system itself.

[Translation done.]

*** NOTICES ***

JPO and NCIP are not responsible for any damages caused by the use of this translation.

- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.*** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

EFFECT OF THE INVENTION

[Effect of the Invention] As mentioned above, according to the chemical trial data management system of this invention, what the staff of 2 – trinomial had taken the time amount for three months or more conventionally comes to be completed by 1 ***** by performing the check of the 2nd henceforth of operation automatically. Therefore, not only the periodical check of operation in systems operation but when it updates operation system and other software which is not in cooperation, a check of operation can be performed frequently and GLP etc. can be guaranteed certainly. Moreover, since a check of operation can be carried out at eye the top, a general aviation can be used now and the introductory cost of a system can be reduced sharply.

[Translation done.]

*** NOTICES ***

JPO and NCIP are not responsible for any damages caused by the use of this translation.

- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.*** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]

[0009] However, by the conventional system, the check of operation had to take remarkable time amount and time and effort, and it had to carry out over the time amount for three months or more at the staff of 2 – trinomial in the usual system. For this reason, although the acceptance inspection at the time of system installation is conducted, once a system begins operation, the actual condition is that the periodical check of operation etc. was not performed at all. The software itself had become what also has the introductory, very high cost of a system from such a situation, in order that [this] at least update of operation system or other software which is not in cooperation might prepare a special-purpose machine substantially since a check of operation is needed if a general aviation is used although it can be used by general-purpose hardware.

[0010] This invention was made in view of such a situation, performs the check of operation in systems operation automatically, and aims at offer of the chemical trial data management system which can guarantee GLP etc. certainly.

[Translation done.]

*** NOTICES ***

JPO and NCIP are not responsible for any damages caused by the use of this translation.

- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.**** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

MEANS

[Means for Solving the Problem] In order to attain the above-mentioned purpose, the chemical trial data management system of this invention A procedure storage means to manage data, such as symptom change of the living body at the time of medicating a living body with a chemical, and to be a chemical trial data management system and to memorize the procedure of a check of operation, A check activation means to perform a check of operation automatically according to the procedure of the check of operation memorized by the storing means and the above-mentioned procedure storage means as a result of storing the result of the above-mentioned check of operation, Let it be a summary to have the contrast means, as a result of contrasting the result of the check of operation by the above-mentioned check activation means with the result of the check of operation in which it is stored by the result storing means.

[0012] Namely, the chemical trial data management system of this invention As a result of storing a procedure storage means to memorize the procedure of a check of operation, and the result of the above-mentioned check of operation, a storing means, It has the contrast means, as a result of contrasting with the result of the check of operation in which the result of the check of operation by check activation means to perform a check of operation automatically according to the procedure of the check of operation memorized by the above-mentioned procedure storage means, and the above-mentioned check activation means is stored by the result storing means. For this reason, that inspection result is both stored as if the procedure of the check of operation on the occasion of the acceptance inspection at the time of system installation is memorized for example. And from the 2nd check of operation, a check activation means can perform a check of operation automatically, and an inspection result can be judged as contrasted with the result of the check of operation at the time of the system installation in which the result is stored by the result storing means.

[0013] Thus, what the staff of 2 - trinomial had taken the time amount for three months or more conventionally comes to be completed by 1 ***** by performing the check of the 2nd henceforth of operation automatically. Therefore, not only the periodical check of operation in systems operation but when it updates operation system and other software which is not in cooperation, a check of operation can be performed frequently and GLP etc. can be guaranteed certainly. Moreover, since a check of operation can be carried out at eye the top, a general aviation can be used now and the introductory cost of a system can be reduced sharply.

[0014] While memorizing the procedure of a check of operation in which a procedure storage means is performed at the time of system installation, in the chemical trial data management system of this invention In storing the result of the check of a result storing means of operation at the time of the above-mentioned system installation In order to memorize the procedure of the check of operation inevitably performed at the time of a receiving inspection and to perform the check of the 2nd henceforth of operation, Even if it is not a uniform package system but the system customized for every system acceptance place, a required check of operation can be automatically performed for every acceptance place 2nd henceforth.

[0015] In the chemical trial data management system of this invention, since data processing with the huge and various toxicity test of the chemical which used the animal as a living body is required to be what is used for the toxicity test of the chemical using the animal as a living body, the effectiveness that it is called for that the introductory cost of a system is low and it can use a general aviation is remarkable, and effective.

[0016]

[Embodiment of the Invention] Below, the gestalt of operation of this invention is explained in detail.

[0017] Drawing 1 is the system configuration Fig. showing the gestalt of 1 operation of the chemical trial data management system of this invention. This system is equipped with the data storage section 7 which stores

the inputted data, a total result, etc. via a data input means 3 to input various kinds of data, such as an amount, clinical findings, etc. of the weight when actually medicating an animal with a chemical, food, water, urine, etc., a data-processing means 4 to receive the data inputted into this data input means 3, and to process a total etc., and the above-mentioned data-processing means 4. In drawing, 13 is storage, such as a hard disk, and 14 is the computer apparatus equipped with a central processing unit, memory, etc.

[0018] Moreover, the display 6 which displays various kinds of information as a data output means 5 to output to a document etc. the data to which the total etc. was carried out with the above-mentioned data-processing means 4, at the time of a data input and data output is formed.

[0019] Here, the usual employment is performed by each means which mentioned the above-mentioned system above. Moreover, the acceptance inspection conducted at the time of the system installation before going into employment of a system actually inputs various kinds of data into the data input means 3, makes a total etc. carry out to the data-processing means 4, and it is conducted by leaving the obtained exact total result as record while checking that an exact total result is obtained.

[0020] The result of an acceptance inspection is saved also as electronic forms outputted from the data output means while being stored in the result storing means 11 and kept.

[0021] And a procedure storage means 8 to memorize the procedure of the check of operation at the time of the acceptance inspection mentioned above, and a check activation means 9 to read the verification procedure of operation memorized by this procedure storage means 8, and to perform automatically are formed in the above-mentioned system. With this check activation means 9, the check of the 2nd henceforth of operation is performed after acceptance-inspection termination by the same procedure as the above-mentioned acceptance inspection at the time of arbitration.

[0022] Moreover, the check result of operation performed with the above-mentioned check activation means 9 is received, and as a result of contrasting with the check result of operation at the time of the acceptance inspection stored in the result storing means 11, the contrast means 10 is formed in the above-mentioned system. Furthermore, the check result storing section 12 which stores in the above-mentioned system the contrast result contrasted with the result contrast means 10 with a check result of operation is formed. Moreover, the above-mentioned contrast result and a check result of operation are outputted from the data output means 5.

[0023] Below, actuation of the above-mentioned chemical trial data management system is explained based on the flow chart shown in drawing 2. In addition, in drawing, "S" means a step.

[0024] First, an acceptance inspection is started at the time of installation of a system (S1). By this acceptance inspection, it checks that data of weight, food, water, urine, etc., such as an amount and pathological findings, are inputted into the data input means 3, make a total etc. carry out to the data-processing means 4, and an exact total result is obtained.

[0025] At this time, storage of the operations sequence of the above-mentioned acceptance inspection is performed with the procedure storage means 8 (S2). Specifically, the procedure of processings, such as a total of the data inputted as data inputs, such as weight, food, and water, is memorized. And after the exact total result of the inputted data is checked and an acceptance inspection is completed, the check result of operation in an acceptance inspection is stored in the result storing means 11 (S3).

[0026] Termination of an acceptance inspection starts actual operation of a system (S4). And employment of a system is continued within the usual business, without performing the check of the 2nd henceforth of operation.

[0027] When performing the check of the 2nd henceforth of operation, the verification procedure of operation at the time of the acceptance inspection memorized by the procedure storage means is read (S5-S6), and processing of a total of the data which are the completely same procedure as the acceptance inspection performed, and were inputted as data inputs, such as weight, food, and water, by the check activation means 9 etc. is performed (S7).

[0028] And contrasting with the check result of the acceptance inspection in which this check result of operation is stored by the result storing means 11 of operation with the contrast means 10 a result is performed after activation of a check of operation (S8). Here, in this check of operation, the judgment of whether the same result as the check result of operation at the time of an acceptance inspection was obtained is performed automatically.

[0029] Subsequently, storing and saving them in (S9) check result storing section 12, while outputting this

check result of operation and contrast result with the data output means 5 is performed (S10). And return and the usual systems operation are again started by step 4.

[0030] Thus, according to the above-mentioned chemical trial data management system, what the staff of 2 - trinomial had taken the time amount for three months or more conventionally comes to be completed by 1 ***** by performing the check of the 2nd henceforth of operation automatically. Therefore, not only the periodical check of operation in systems operation but when it updates operation system and other software which is not in cooperation, a check of operation can be performed frequently and GLP etc. can be guaranteed certainly. Moreover, since a check of operation can be carried out at eye the top, a general aviation can be used now and the introductory cost of a system can be reduced sharply.

[0031] Moreover, in order to memorize the procedure of the check of operation inevitably performed at the time of a receiving inspection and to perform the check of the 2nd henceforth of operation, even if it is not a uniform package system but the system customized for every system acceptance place, a required check of operation can be automatically performed for every acceptance place 2nd henceforth.

[0032] Such a chemical trial data management system is used suitable for the toxicity test of the chemical which used the animal as a living body. It is because the effectiveness that it is called for that the introductory cost of a system is low and it can use a general aviation since data processing with the huge and various toxicity test of the chemical using the animal as a living body is required is remarkable and effective.

[0033] In addition, although the check result of the acceptance inspection at the time of system installation of operation is stored in the result storing means 11 and the check result of operation was contrasted with the check result of operation at the time of the above-mentioned acceptance inspection in the check of the 2nd henceforth of operation with the gestalt of the above-mentioned implementation The check result of the 2nd henceforth of operation is stored in the storing means 11 each time, and you may make it contrast a check result of operation with the last check result of operation in a next check of operation not the thing to limit to this but a result.

[0034] Moreover, although the verification procedure of the acceptance inspection at the time of system installation of operation is memorized for the procedure storage means 8 and the operations sequence at the time of the above-mentioned acceptance inspection was made to perform a check of operation for it in the check of the 2nd henceforth of operation with the gestalt of the above-mentioned implementation The verification procedure of the 2nd henceforth of operation is memorized for the procedure storage means 8 instead of what is limited to this each time, and it may be made to carry out a check of operation to it by the last verification procedure of operation in a next check of operation.

[0035] Moreover, the system of this invention is applicable to the toxicity test of the chemical which used the animal as a living body, a drug effect pharmacological test and a general pharmacological test before going into the safety test by the animal, a drug dynamic body trial, or the clinical trial to which GCP (Good Clinical Practice of drugs) is applied. Moreover, applying to the trial of non-GLP is also possible. The same operation effectiveness is done so also by these cases.

[0036] In addition, in this invention, a chemical is the meaning which is not limited to drugs and contains various kinds of chemicals including agricultural chemicals, a food additive, and skin external preparations.

[Translation done.]

*** NOTICES ***

JPO and NCIPi are not responsible for any damages caused by the use of this translation.

- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.*** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1] It is the system configuration Fig. showing the gestalt of 1 operation of the chemical trial data management system of this invention.

[Drawing 2] It is a flow chart Fig. explaining actuation of the above-mentioned chemical trial data management system.

[Description of Notations]

8 Procedure Storage Means

9 Check Activation Means

10 Result Contrast Means

11 Result Storing Means

[Translation done.]

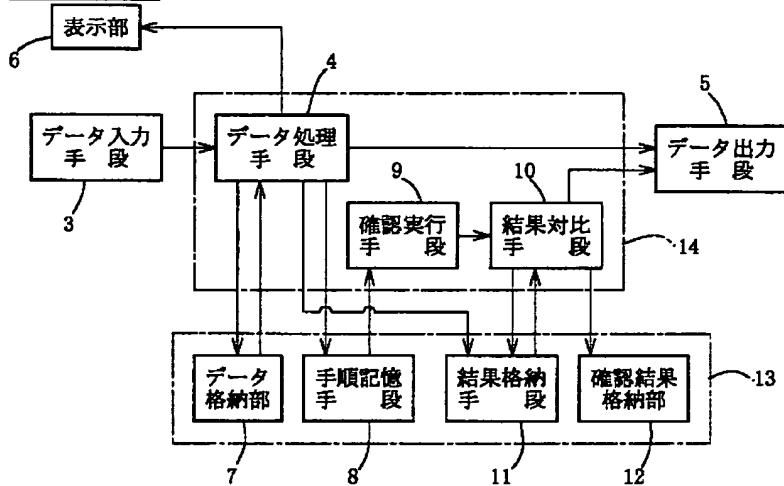
* NOTICES *

JPO and NCIPi are not responsible for any damages caused by the use of this translation.

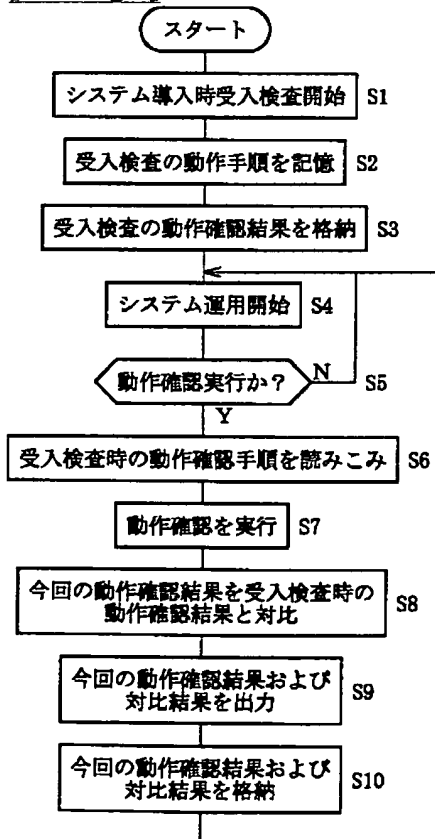
- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.**** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

DRAWINGS

[Drawing 1]



[Drawing 2]



[Translation done.]

THIS PAGE BLANK (USPTO)

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record.**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☐ **BLACK BORDERS**

☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**

☐ **FADED TEXT OR DRAWING**

☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**

☐ **SKEWED/SLANTED IMAGES**

☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**

☐ **GRAY SCALE DOCUMENTS**

☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**

☒ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.